ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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Grantor: CDER IND/IDE Number: 51-222 Serial Number:

A Degarelix Trial in Patients With Prostate Cancer

This study has been terminated.
(Inadequate recruitment resulting in a too low patient number for collection of long term efficacy data.)

Sponsor:	Ferring Pharmaceuticals
Collaborators:	
Information provided by (Responsible Party):	Ferring Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT01242748

Purpose

A phase III extension trial comparing the efficacy and safety of degarelix 3 month depot with the established therapy Zoladex 3 month implant in patients with prostate cancer.

Condition	Intervention	Phase
Prostate Cancer	Drug: Degarelix Drug: Goserelin acetate	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, Non-Randomized, Safety/Efficacy Study
Official Title: An Open-label, Multi-Centre, Extension Trial, Evaluating the Long-Term Progression-Free Survival of Degarelix or Goserelin Three-Month Dosing Regimens in Patients With Prostate Cancer Requiring Androgen Deprivation Therapy

Further study details as provided by Ferring Pharmaceuticals:

Primary Outcome Measure:

- Hazard Ratio of Prostate-specific Antigen (PSA) Progression-free Survival (PFS) Failure Rates During 3 Years' Treatment Between Degarelix and Goserelin [Time Frame: From baseline to 3 years] [Designated as safety issue: No]

PSA PFS failure is defined as either PSA failure (defined as increase in serum PSA of 50%, and at least 5 ng/mL, compared to nadir, measured on two consecutive occasions at least 2 weeks apart) or death, whichever is first. The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of no PSA-PFS.

Secondary Outcome Measures:

- Hazard Ratio of PFS Failure Rates During 3 Years Treatment Between Degarelix and Goserelin [Time Frame: From baseline to 3 years] [Designated as safety issue: No]
  PFS failure is defined as either PSA failure, introduction of additional therapy related to prostate cancer (radiation, anti-androgens or second-line treatment), or death, whichever is first. The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of no PFS failure.
- Hazard Ratio of PSA Failure Rates During 3 Years Treatment Between Degarelix and Goserelin [Time Frame: From baseline to 3 years] [Designated as safety issue: No]
  PSA failure is defined as increase in serum PSA of 50%, and at least 5 ng/mL, compared to nadir, measured on two consecutive occasions at least 2 weeks apart. The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of no PSA failure.
- Hazard Ratio of Testosterone Escape Rates During 3 Years' Treatment Between Degarelix and Goserelin [Time Frame: From baseline to 3 years] [Designated as safety issue: No]
  Testosterone escape is defined as serum levels >0.5 ng/mL. The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of no testosterone escape.
- Hazard Ratio of the Rates of Introduction of Additional Therapy Related to Prostate Cancer During 3 Years' Treatment Between Degarelix and Goserelin [Time Frame: From baseline to 3 years] [Designated as safety issue: No]
  Additional therapy related to prostate cancer included radiation, anti-androgens and second-line treatment. The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of no additional therapy related to prostate cancer.
- Hazard Ratio of Mortality Rates During 3 Years' Treatment Between Degarelix and Goserelin [Time Frame: From baseline to 3 years] [Designated as safety issue: No]
  The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of death.
- Serum Levels of Testosterone During 3 Years' Treatment With Degarelix or Goserelin [Time Frame: Baseline and after 1, 6, 12, 19, and 22 months] [Designated as safety issue: No]
  Median testosterone levels are presented as absolute values in nanograms per milliliter (ng/mL) at baseline and after 1, 6, 12, 19, and 22 months. One month equals 28 days. After 22 months, only a limited number of samples were analysed.
- Serum Levels of Prostate-specific Antigen (PSA) During 3 Years' Treatment With Degarelix or Goserelin [Time Frame: Baseline and after 1, 6, 12, 19, and 22 months] [Designated as safety issue: No]
  Median PSA levels are presented as absolute values in nanograms per milliliter (ng/mL) at baseline and after 1, 6, 12, 19, and 22 months. One month equals 28 days. After 22 months, only a limited number of samples were analysed.

Enrollment: 288
Study Start Date: October 2010
Primary Completion Date: December 2011
Study Completion Date: January 2012

Arms	Assigned Interventions
Experimental: Degarelix 240 mg/480 mg	Drug: Degarelix The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One

Arms	Assigned Interventions
	month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months. Other Names: Firmagon FE200486
Active Comparator: Goserelin acetate	Drug: Goserelin acetate The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months. Other Names: Zoladex

Detailed Description:

CS35A was an open-label, multicentre, comparative non-inferiority extension trial to the Phase 3 CS35 trial (NCT00946920).

In the main CS35 trial, participants were randomised 2:1 to treatment with degarelix or goserelin, respectively. All participants who completed the main CS35 trial after initiation of the CS35A trial were eligible to enrol into this extension trial, provided that their treatment could continue uninterrupted. Patients entering the CS35A trial continued with the same 3-monthly treatment as they received in CS35 (i.e. degarelix 480 mg or goserelin 10.8 mg).

It was intended that patients enrolled in the CS35A trial would receive treatment with degarelix or goserelin at 3-month intervals for a period of 40 months (including 13 months' treatment in CS35). It was, however, decided to prematurely terminate the CS35A trial due to an insufficient number of patients being enrolled. Maximum exposure of treatment was 111 weeks (in both treatment arms).

The baseline characteristics are based on the CS35A Full Analysis Set (FAS)defined as all participants who received at least one dose of degarelix or goserelin acetate during CS35A and had at least one efficacy assessment after dosing. All efficacy analyses were performed for the CS35/CS35A FAS defined as all participants who received at least one dose of degarelix or goserelin acetate during CS35 and had at least one efficacy assessment after dosing. All safety analyses were performed for the CS35/CS35A Safety analysis set, which included all patients who received at least one dose of degarelix or goserelin acetate during CS35.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Male
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Has given written consent prior to any trial-related activity is performed. (A trial-related activity is defined as any procedure that would not have been performed during the normal management of the patient).
- Has completed the CS35 trial.

Exclusion Criteria:

- Has been withdrawn from the CS35 trial.
- Has had end of trial visit in CS35 prior to approval of the CS35A protocol.

Contacts and Locations

Locations

United States, Colorado
University of Colorado School of Medicine
Aurora, Colorado, United States
The Urology Center of Colorado
Denver, Colorado, United States
United States, Delaware
Urology Associates of Dover, PA
Dover, Delaware, United States
United States, Florida
South Florida Medical Research
Aventura, Florida, United States
United States, New Mexico
Urology Group of New Mexico, PC
Albuquerque, New Mexico, United States
United States, South Carolina
Carolina Urologic Research Center
Myrtle Beach, South Carolina, United States
United States, Texas
Urology San Antonio Research, Pa
San Antonio, Texas, United States
United States, Washington
Seattle Urology Research Center
Burien, Washington, United States

Belgium
- AZ Groeninge - Campus Sint-Maarten
  - Kortrijk, Belgium

Canada
- Southern Interior Medical Research Inc.
  - Kelowna, Canada
- Mor Urology, Inc.
  - Newmarket, Canada
- Investigational site
  - Scarborough, Canada
- Investigational site
  - Toronto, Canada

Canada, Ontario
- Jonathan Giddens Medicine Professional Corporation
  - Brampton, Ontario, Canada

Czech Republic
- Urocentrum Brno
  - Brno, Czech Republic
- Nemocnice Jindrichuv Hradec, a.s.
  - Jindrichuv Hradec, Czech Republic
- Kromerizska nemocnice a.s.
  - Kromeriz, Czech Republic
- Vseobecna fakultni nemocnice v Praze, Praha 2
  - Praha, Czech Republic
- Fakultni nemocnice v Motole, Praha 5
  - Praha, Czech Republic
- Krajska nemocnice T. Bati a.s.
  - Zlin, Czech Republic

Finland
- ODL Terveys Oy
  - Oulu, Finland
- Pohjois-Karjalan keskussairaala
  - Tampere, Finland
- Tampereen yliopistollinen sairaala
  - Tampere, Finland

Germany
- Gemeinschaftspraxis Rudolph & Wörner
  - Kirchheim, Germany
- Urologische Studienpraxis
  - Nürtingen, Germany

Hungary
- Semmelweis Egyetem
  - Budapest, Hungary
- Fővárosi Önkormányzat Bajcsy-Zsilinszky Kórház
  - Budapest, Hungary

Fővárosi Önkormányzat uzsoki utcai Kórház
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Dombóvári Szent Lukács Egészségügyi Nonprofit Kft.
Dombóvár, Hungary
Borsod-Abaúj-Zemplén Megyei Kórház és Egyetemi Oktató Kórház
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Pécs, Hungary
Szegedi Tudományegyetem Szent-Györgyi Albert Klinikai Központ
Szeged, Hungary
Jávorszky Ödön Kórház
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Chihuahua, Chih., Mexico
Hospital Angeles Culiacan
Culiacan, Sinaloa, Mexico
Consultorio de Especialidad en Urologia Privado
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Médica Sur, S.A.B. de C.V.
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Hospital Angeles Lindavista
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Bielsko-Biala, Poland
Wojewodzki Szpital Specjalistyczny im. Janusza Korczaka w Slupsku
Slupsk, Poland
Romania
Private Medical Center SRL
Arad, Romania
Brasov Emergency Clinical County Hospital
Brasov, Romania
"Prof. Dr. Th. Burghele" Clinical Hospital

Bucharest, Romania
"Sfantul Ioan" Emergency Clinical Hospital
Bucharest, Romania
Fundeni Clinical Institute of Uronephrology and Renal Transplantation
Bucharest, Romania
Dinu Uromedica
Bucharest, Romania
PROVITA 2000 Medical Center
Constanta, Romania
"Dr. C.I. Parhon" Clinical Hospital
Iasi, Romania
Vita Care Flav Medical Center
Pitesti, Romania
Sibiu Emergency Clinical County Hospital
Sibiu, Romania
Ukraine
Dnipropetrovsk State Medical Academy
Dnipropetrovsk, Ukraine
Donetsk Regional Clinical Territorial Medical Association
Donetsk, Ukraine
Regional Clinical Center of Urology and Nephrology n.a. V.I.Shapoval
Kharkiv, Ukraine
Kyiv City Clinical Hospital #3
Kyiv, Ukraine
Odesa Regional Clinical Hospital
Odesa, Ukraine
Municipal Institution "Zaporizhzhia Regional Clinical Hospital"
Zaporizhzhya, Ukraine
United Kingdom
Ipswich Hospital
Ipswich, United Kingdom
The Royal Marsden NHS Foundation Trust
Sutton, United Kingdom

Investigators

Study Director:	Clinical Development Support	Ferring Pharmaceuticals

More Information

Responsible Party:	Ferring Pharmaceuticals
Study ID Numbers:	FE200486 CS35A 2010-021434-55 [EudraCT Number]
Health Authority:	United States: Food and Drug Administration Canada: Health Canada

Mexico: Ministry of Health
Belgium: Federal Agency for Medicinal Products and Health Products
Czech Republic: State Institute for Drug Control
Finland: Finnish Medicines Agency
Germany: Federal Institute for Drugs and Medical Devices
Hungary: National Institute of Pharmacy
Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)
Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Romania: National Medicines Agency
Ukraine: State Pharmacological Center - Ministry of Health
United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study Results

Participant Flow

Recruitment Details	All participants who completed the main CS35 trial after initiation of the CS35A extension trial were eligible to enrol into CS35A.
Pre-Assignment Details	Participants entering the CS35A trial continued with the same 3-monthly treatment as they received in CS35 (i.e. degarelix 480 mg or goserelin 10.8 mg).

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Overall Study

	Degarelix 240 mg/480 mg	Goserelin Acetate
Started	194 [1]	94
CS35/CS35A Safety Analysis Set	565 [2]	283
CS35/CS35A Full Analysis Set (FAS)	565 [3]	282
Completed	156 [4]	80
Not Completed	38	14
Adverse Event	10	5
Lost to Follow-up	6	2
Physician Decision	3	2
Protocol Violation	1	0
Withdrawal by Subject	10	2
Miscellaneous reasons	8	3

[1] Enrolled in CS35A, CS35A Full Analysis Set.
[2] Received at least 1 dose of trial drug during the main CS35 trial.
[3] Received at least 1 dose of trial drug during CS35+had at least 1 efficacy assessment after dosing.
[4] These participants were ongoing when the trial was closed by the Sponsor.

Baseline Characteristics

Analysis Population Description
CS35A Full Analysis Set

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.

	Description
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Baseline Measures

	Degarelix 240 mg/480 mg	Goserelin Acetate	Total
Number of Participants	194	94	288
Age, Continuous [units: years] Mean (Standard Deviation)	73.1 (8.4)	71.3 (7.0)	72.5 (8.0)
Gender, Male/Female [units: participants]			
Female	0	0	0
Male	194	94	288
Race (NIH/OMB) [units: participants]			
American Indian or Alaska Native	34	21	55
Asian	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5	5	10
White	154	68	222
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Median Baseline Serum Testosterone Levels [units: nanogram per milliliter (ng/mL)] Median (Full Range)	4.41 (0.68 to 13.3)	4.65 (1.55 to 13.2)	4.52 (0.68 to 13.3)

	Degarelix 240 mg/480 mg	Goserelin Acetate	Total
Median Baseline Serum Prostate-specific Antigen Levels [units: ng/mL] Median (Full Range)	20.6 (0.4 to 8762)	16.6 (1.49 to 12961)	18.7 (0.4 to 12961)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Hazard Ratio of Prostate-specific Antigen (PSA) Progression-free Survival (PFS) Failure Rates During 3 Years' Treatment Between Degarelix and Goserelin
Measure Description	PSA PFS failure is defined as either PSA failure (defined as increase in serum PSA of 50%, and at least 5 ng/mL, compared to nadir, measured on two consecutive occasions at least 2 weeks apart) or death, whichever is first. The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of no PSA-PFS.
Time Frame	From baseline to 3 years
Safety Issue?	No

Analysis Population Description

CS35 (NCT00946920)/CS35A Full Analysis Set (degarelix n=565; goserelin n=282). The analysis population was pre-specified in the study protocol and statistical analysis plan.

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Measured Values

	Degarelix 240 mg/480 mg	Goserelin Acetate
Number of Participants Analyzed	565	282
Hazard Ratio of Prostate-specific Antigen (PSA) Progression-free Survival (PFS) Failure Rates During 3 Years' Treatment Between Degarelix and Goserelin [units: percentage of no PSA-PFS] Number (95% Confidence Interval)	75.5 (69.1 to 80.7)	75.4 (64.5 to 83.4)

Statistical Analysis 1 for Hazard Ratio of Prostate-specific Antigen (PSA) Progression-free Survival (PFS) Failure Rates During 3 Years' Treatment Between Degarelix and Goserelin

Statistical Analysis Overview	Comparison Groups	Degarelix 240 mg/480 mg, Goserelin Acetate
	Comments	The hazard ratio of PSA PFS failure rates was estimated using the Cox proportional hazard model with time to PSA PFS failure as dependent and treatment as independent variables and adjusted for baseline PSA category, prostate cancer stage, weight and geographical region. Degarelix was to be considered non-inferior to goserelin if the upper limit of the two-sided 95% confidence interval (CI) of the adjusted hazard ratio was less than or equal to the non-inferiority margin of 1.33.
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	Degarelix was considered to be non-inferior to goserelin with regard to the hazard ratio of PSA PFS failure rates as the upper limit of the two-sided 95% CI of the adjusted hazard ratio was less than the non-inferiority margin of 1.33.

Statistical Test of Hypothesis	P-Value	0.1589
	Comments	[Not specified]
	Method	Other [Cox proportional hazard model]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.774
	Confidence Interval	(2-Sided) 95% 0.542 to 1.106
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Hazard Ratio of PFS Failure Rates During 3 Years Treatment Between Degarelix and Goserelin
Measure Description	PFS failure is defined as either PSA failure, introduction of additional therapy related to prostate cancer (radiation, anti-androgens or second-line treatment), or death, whichever is first. The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of no PFS failure.
Time Frame	From baseline to 3 years
Safety Issue?	No

Analysis Population Description

CS35 (NCT00946920)/CS35A Full Analysis Set (degarelix n=565; goserelin n=282). The analysis population was pre-specified in the study protocol and statistical analysis plan.

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Measured Values

	Degarelix 240 mg/480 mg	Goserelin Acetate
Number of Participants Analyzed	565	282
Hazard Ratio of PFS Failure Rates During 3 Years Treatment Between Degarelix and Goserelin [units: percentage of no PFS failure] Number (95% Confidence Interval)	71.5 (66.0 to 76.2)	69.0 (58.0 to 77.7)

Statistical Analysis 1 for Hazard Ratio of PFS Failure Rates During 3 Years Treatment Between Degarelix and Goserelin

Statistical Analysis Overview	Comparison Groups	Degarelix 240 mg/480 mg, Goserelin Acetate
	Comments	The hazard ratio was estimated using the Cox proportional hazard model.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1244
	Comments	[Not specified]
	Method	Other [Cox proportional hazard model]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.783
	Confidence Interval	(2-Sided) 95% 0.574 to 1.070
	Estimation Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Hazard Ratio of PSA Failure Rates During 3 Years Treatment Between Degarelix and Goserelin
Measure Description	PSA failure is defined as increase in serum PSA of 50%, and at least 5 ng/mL, compared to nadir, measured on two consecutive occasions at least 2 weeks apart. The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of no PSA failure.
Time Frame	From baseline to 3 years
Safety Issue?	No

Analysis Population Description

CS35 (NCT00946920)/CS35A Full Analysis Set (degarelix n=565; goserelin n=282). The analysis population was pre-specified in the study protocol and statistical analysis plan.

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Measured Values

	Degarelix 240 mg/480 mg	Goserelin Acetate
Number of Participants Analyzed	565	282
Hazard Ratio of PSA Failure Rates During 3 Years Treatment Between Degarelix and Goserelin [units: percentage of no PSA failure] Number (95% Confidence Interval)	77.5 (71.0 to 82.7)	79.6 (68.9 to 86.9)

Statistical Analysis 1 for Hazard Ratio of PSA Failure Rates During 3 Years Treatment Between Degarelix and Goserelin

Statistical Analysis Overview	Comparison Groups	Degarelix 240 mg/480 mg, Goserelin Acetate
	Comments	The hazard ratio was estimated using the Cox proportional hazard model.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.856
	Confidence Interval	(2-Sided) 95% 0.580 to 1.263
	Estimation Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Hazard Ratio of Testosterone Escape Rates During 3 Years' Treatment Between Degarelix and Goserelin
Measure Description	Testosterone escape is defined as serum levels >0.5 ng/mL. The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of no testosterone escape.
Time Frame	From baseline to 3 years
Safety Issue?	No

Analysis Population Description

CS35 (NCT00946920)/CS35A Full Analysis Set (degarelix n=565; goserelin n=282). The analysis population was pre-specified in the study protocol and statistical analysis plan.

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Measured Values

	Degarelix 240 mg/480 mg	Goserelin Acetate
Number of Participants Analyzed	565	282
Hazard Ratio of Testosterone Escape Rates During 3 Years' Treatment Between Degarelix and Goserelin [units: percentage of no testosterone escape] Number (95% Confidence Interval)	83.7 (77.4 to 88.4)	96.7 (93.7 to 98.2)

Statistical Analysis 1 for Hazard Ratio of Testosterone Escape Rates During 3 Years' Treatment Between Degarelix and Goserelin

Statistical Analysis Overview	Comparison Groups	Degarelix 240 mg/480 mg, Goserelin Acetate
	Comments	The hazard ratio was estimated using the Cox proportional hazard model.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0005
	Comments	[Not specified]
	Method	Other [Cox proportional hazard model]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	3.511
	Confidence Interval	(2-Sided) 95% 1.739 to 7.090
	Estimation Comments	[Not specified]

5. Secondary Outcome Measure:

Measure Title	Hazard Ratio of the Rates of Introduction of Additional Therapy Related to Prostate Cancer During 3 Years' Treatment Between Degarelix and Goserelin
Measure Description	Additional therapy related to prostate cancer included radiation, anti-androgens and second-line treatment. The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of no additional therapy related to prostate cancer.
Time Frame	From baseline to 3 years
Safety Issue?	No

Analysis Population Description

CS35 (NCT00946920)/CS35A Full Analysis Set (degarelix n=565; goserelin n=282). The analysis population was pre-specified in the study protocol and statistical analysis plan.

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Measured Values

	Degarelix 240 mg/480 mg	Goserelin Acetate
Number of Participants Analyzed	565	282
Hazard Ratio of the Rates of Introduction of Additional Therapy Related to Prostate Cancer During 3 Years' Treatment Between Degarelix and Goserelin [units: percentage of no additional therapy] Number (95% Confidence Interval)	84.5 (80.0 to 88.1)	83.4 (77.3 to 88.0)

Statistical Analysis 1 for Hazard Ratio of the Rates of Introduction of Additional Therapy Related to Prostate Cancer During 3 Years' Treatment Between Degarelix and Goserelin

Statistical Analysis Overview	Comparison Groups	Degarelix 240 mg/480 mg, Goserelin Acetate
	Comments	The hazard ratio was estimated using the Cox proportional hazard model.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.143
	Comments	[Not specified]
	Method	Other [Cox proportional hazard model]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.739
	Confidence Interval	(2-Sided) 95% 0.493 to 1.108
	Estimation Comments	[Not specified]

6. Secondary Outcome Measure:

Measure Title	Hazard Ratio of Mortality Rates During 3 Years' Treatment Between Degarelix and Goserelin
Measure Description	The number below present the unadjusted rates (estimated using the Kaplan-Meier method) of death.
Time Frame	From baseline to 3 years
Safety Issue?	No

Analysis Population Description

CS35 (NCT00946920)/CS35A Full Analysis Set (degarelix n=565; goserelin n=282). The analysis population was pre-specified in the study protocol and statistical analysis plan.

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Measured Values

	Degarelix 240 mg/480 mg	Goserelin Acetate
Number of Participants Analyzed	565	282
Hazard Ratio of Mortality Rates During 3 Years' Treatment Between Degarelix and Goserelin [units: percentage of deaths]	4.6 (2.4 to 8.5)	5.3 (2.6 to 10.5)

	Degarelix 240 mg/480 mg	Goserelin Acetate
Number (95% Confidence Interval)		

Statistical Analysis 1 for Hazard Ratio of Mortality Rates During 3 Years' Treatment Between Degarelix and Goserelin

Statistical Analysis Overview	Comparison Groups	Degarelix 240 mg/480 mg, Goserelin Acetate
	Comments	The hazard ratio was estimated using the Cox proportional hazard model.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2212
	Comments	[Not specified]
	Method	Other [Cox proportional hazard model]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.595
	Confidence Interval	(2-Sided) 95% 0.259 to 1.368
	Estimation Comments	[Not specified]

7. Secondary Outcome Measure:

Measure Title	Serum Levels of Testosterone During 3 Years' Treatment With Degarelix or Goserelin
Measure Description	Median testosterone levels are presented as absolute values in nanograms per milliliter (ng/mL) at baseline and after 1, 6, 12, 19, and 22 months. One month equals 28 days. After 22 months, only a limited number of samples were analysed.
Time Frame	Baseline and after 1, 6, 12, 19, and 22 months
Safety Issue?	No

Analysis Population Description

CS35 (NCT00946920)/CS35A Full Analysis Set (degarelix n=565; goserelin n=282). The analysis population was pre-specified in the study protocol and statistical analysis plan.

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Measured Values

	Degarelix 240 mg/480 mg	Goserelin Acetate
Number of Participants Analyzed	565	282
Serum Levels of Testosterone During 3 Years' Treatment With Degarelix or Goserelin [units: ng/mL] Median (Full Range)		
Baseline	4.52 (0.56 to 14.5)	4.62 (0.07 to 13.2)
Month 1	0.10 (0.015 to 3.85)	0.16 (0.04 to 1.77)
Month 6	0.09 (0.015 to 1.57)	0.09 (0.015 to 0.32)
Month 12	0.10 (0.015 to 1.1)	0.09 (0.015 to 0.44)
Month 19	0.11 (0.05 to 2.22)	0.05 (0.05 to 0.43)
Month 22	0.11 (0.05 to 3.4)	0.05 (0.05 to 0.23)

8. Secondary Outcome Measure:

Measure Title	Serum Levels of Prostate-specific Antigen (PSA) During 3 Years' Treatment With Degarelix or Goserelin
Measure Description	Median PSA levels are presented as absolute values in nanograms per milliliter (ng/mL) at baseline and after 1, 6, 12, 19, and 22 months. One month equals 28 days. After 22 months, only a limited number of samples were analysed.
Time Frame	Baseline and after 1, 6, 12, 19, and 22 months

Safety Issue?	No

Analysis Population Description

CS35 (NCT00946920)/CS35A Full Analysis Set (degarelix n=565; goserelin n=282). The analysis population was pre-specified in the study protocol and statistical analysis plan.

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Measured Values

	Degarelix 240 mg/480 mg	Goserelin Acetate
Number of Participants Analyzed	565	282
Serum Levels of Prostate-specific Antigen (PSA) During 3 Years' Treatment With Degarelix or Goserelin [units: ng/mL] Median (Full Range)		
Baseline	19 (0.26 to 8762)	19.1 (0.005 to 12961)
Month 1	3.79 (0.03 to 1540)	6.5 (0.005 to 645)
Month 6	0.82 (0.005 to 2648)	0.73 (0.005 to 607)
Month 12	0.6 (0.005 to 6889)	0.43 (0.005 to 1802)
Month 19	0.54 (0.005 to 712)	0.28 (0.005 to 1150)
Month 22	0.535 (0.005 to 252)	0.26 (0.005 to 646)

Reported Adverse Events

Time Frame	Adverse events were recorded from signed informed consent until the last visit (maximum 111 weeks of treatment).
Additional Description	Adverse events were evaluated at each visit. The analysis population was the CS35/CS35A (NCT00946920)/ CS35A Safety Analysis Set (degarelix n=565; goserelin n=283). The analysis population was pre-specified in the study protocol and statistical analysis plan.

Reporting Groups

	Description
Degarelix 240 mg/480 mg	Degarelix: The degarelix doses were administered by subcutaneous (s.c.) injections into the abdominal wall. In the main CS35 trial, a starting dose of 240 mg degarelix was administered on Day 0. One month later a maintenance dose of 480 mg was administered. This was repeated after 4, 7, and 10 months (ie a total of 5 administrations in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the degarelix treated participants continued to receive degarelix 480 mg s.c. treatment every three months.
Goserelin Acetate	Goserelin acetate: The goserelin doses were administered by subcutaneous (s.c.) implants into the abdominal wall. In the main CS35 trial, an initial dose of 3.6 mg goserelin was administered on Day 0. One month later a subsequent dose of 10.8 mg was administered and this was repeated after 4, 7, and 10 months (ie a total of 5 implants in the main trial). In the CS35A extension trial, the participants received the same treatment as in the main trial ie the goserelin treated participants continued to receive goserelin acetate 10.8 mg s.c. implants every three months.

Serious Adverse Events

	Degarelix 240 mg/480 mg	Goserelin Acetate
	Affected/At Risk (%)	Affected/At Risk (%)
Total	58/565 (10.27%)	33/283 (11.66%)
Blood and lymphatic system disorders		
Anaemia [A] †	2/565 (0.35%)	2/283 (0.71%)
Haemorrhagic anaemia [A] †	1/565 (0.18%)	0/283 (0%)
Cardiac disorders		
Acute myocardial infarction [A] †	2/565 (0.35%)	2/283 (0.71%)
Angina pectoris [A] †	2/565 (0.35%)	0/283 (0%)

	Degarelix 240 mg/480 mg	Goserelin Acetate
	Affected/At Risk (%)	Affected/At Risk (%)
Angina unstable [A] †	0/565 (0%)	1/283 (0.35%)
Atrial fibrillation [A] †	1/565 (0.18%)	1/283 (0.35%)
Cardiac arrest [A] †	1/565 (0.18%)	0/283 (0%)
Cardiac failure [A] †	2/565 (0.35%)	1/283 (0.35%)
Cardiac failure acute [A] †	2/565 (0.35%)	0/283 (0%)
Cardiac failure congestive [A] †	0/565 (0%)	1/283 (0.35%)
Cardiopulmonary failure [A] †	1/565 (0.18%)	0/283 (0%)
Coronary artery disease [A] †	2/565 (0.35%)	1/283 (0.35%)
Myocardial infarction [A] †	1/565 (0.18%)	1/283 (0.35%)
Supraventricular tachycardia [A] †	0/565 (0%)	2/283 (0.71%)
Congenital, familial and genetic disorders		
Phimosis [A] †	0/565 (0%)	1/283 (0.35%)
Eye disorders		
Blindness transient [A] †	1/565 (0.18%)	0/283 (0%)
Cataract [A] †	1/565 (0.18%)	0/283 (0%)
Eye pain [A] †	0/565 (0%)	1/283 (0.35%)
Gastrointestinal disorders		
Abdominal hernia [A] †	1/565 (0.18%)	0/283 (0%)
Dyspepsia [A] †	0/565 (0%)	1/283 (0.35%)
Enterocolitis haemorrhagic [A] †	0/565 (0%)	1/283 (0.35%)
Gastric ulcer haemorrhage [A] †	1/565 (0.18%)	0/283 (0%)
Gastrointestinal haemorrhage [A] †	3/565 (0.53%)	0/283 (0%)

	Degarelix 240 mg/480 mg	Goserelin Acetate
	Affected/At Risk (%)	Affected/At Risk (%)
Inguinal hernia [A] †	2/565 (0.35%)	1/283 (0.35%)
Intestinal obstruction [A] †	2/565 (0.35%)	0/283 (0%)
Pancreatitis [A] †	1/565 (0.18%)	0/283 (0%)
Pancreatitis acute [A] †	0/565 (0%)	1/283 (0.35%)
Rectal haemorrhage [A] †	0/565 (0%)	1/283 (0.35%)
General disorders		
Asthenia [A] †	1/565 (0.18%)	0/283 (0%)
Death [A] †	0/565 (0%)	1/283 (0.35%)
Non-cardiac chest pain [A] †	1/565 (0.18%)	0/283 (0%)
Oedema peripheral [A] †	1/565 (0.18%)	0/283 (0%)
Pyrexia [A] †	0/565 (0%)	1/283 (0.35%)
Sudden cardiac death [A] †	0/565 (0%)	1/283 (0.35%)
Sudden death [A] †	3/565 (0.53%)	0/283 (0%)
Hepatobiliary disorders		
Cholecystitis [A] †	1/565 (0.18%)	0/283 (0%)
Infections and infestations		
Bronchopneumonia [A] †	1/565 (0.18%)	0/283 (0%)
Cellulitis [A] †	1/565 (0.18%)	0/283 (0%)
Gastroenteritis [A] †	1/565 (0.18%)	0/283 (0%)
Infective exacerbation of chronic obstructive airways disease [A] †	1/565 (0.18%)	0/283 (0%)
Injection site abscess [A] †	1/565 (0.18%)	0/283 (0%)
Lobar pneumonia [A] †	1/565 (0.18%)	2/283 (0.71%)

	Degarelix 240 mg/480 mg	Goserelin Acetate
	Affected/At Risk (%)	Affected/At Risk (%)
Lung abscess [A] †	0/565 (0%)	1/283 (0.35%)
Pneumonia [A] †	1/565 (0.18%)	2/283 (0.71%)
Pyelonephritis acute [A] †	1/565 (0.18%)	0/283 (0%)
Pyothorax [A] †	1/565 (0.18%)	0/283 (0%)
Sepsis [A] †	1/565 (0.18%)	1/283 (0.35%)
Staphylococcal bacteraemia [A] †	1/565 (0.18%)	0/283 (0%)
Staphylococcal infection [A] †	1/565 (0.18%)	0/283 (0%)
Urinary tract infection [A] †	1/565 (0.18%)	0/283 (0%)
Injury, poisoning and procedural complications		
Coronary artery reocclusion [A] †	0/565 (0%)	1/283 (0.35%)
Dislocation of joint prosthesis [A] †	1/565 (0.18%)	0/283 (0%)
Humerus fracture [A] †	1/565 (0.18%)	0/283 (0%)
Metabolism and nutrition disorders		
Cachexia [A] †	0/565 (0%)	1/283 (0.35%)
Dehydration [A] †	2/565 (0.35%)	0/283 (0%)
Diabetes mellitus inadequate control [A] †	1/565 (0.18%)	0/283 (0%)
Insulin-requiring type 2 diabetes mellitus [A] †	0/565 (0%)	1/283 (0.35%)
Type 2 diabetes mellitus [A] †	2/565 (0.35%)	0/283 (0%)
Musculoskeletal and connective tissue disorders		
Back pain [A] †	1/565 (0.18%)	0/283 (0%)
Intervertebral disc protrusion [A] †	1/565 (0.18%)	0/283 (0%)
Lumbar spinal stenosis [A] †	0/565 (0%)	1/283 (0.35%)

	Degarelix 240 mg/480 mg	Goserelin Acetate
	Affected/At Risk (%)	Affected/At Risk (%)
Muscular weakness [A] †	1/565 (0.18%)	0/283 (0%)
Osteoarthritis [A] †	0/565 (0%)	1/283 (0.35%)
Pathological fracture [A] †	0/565 (0%)	1/283 (0.35%)
Prostate cancer [A] †	1/565 (0.18%)	0/283 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma [A] †	1/565 (0.18%)	0/283 (0%)
Bile duct cancer [A] †	1/565 (0.18%)	0/283 (0%)
Chronic myelomonocytic leukaemia [A] †	1/565 (0.18%)	0/283 (0%)
Colon cancer [A] †	1/565 (0.18%)	2/283 (0.71%)
Gastric cancer [A] †	1/565 (0.18%)	0/283 (0%)
Intestinal adenocarcinoma [A] †	1/565 (0.18%)	0/283 (0%)
Laryngeal cancer [A] †	1/565 (0.18%)	0/283 (0%)
Lung neoplasm [A] †	1/565 (0.18%)	0/283 (0%)
Metastases to central nervous system [A] †	1/565 (0.18%)	0/283 (0%)
Metastases to liver [A] †	1/565 (0.18%)	0/283 (0%)
Metastases to lung [A] †	2/565 (0.35%)	0/283 (0%)
Metastatic carcinoma of the bladder [A] †	0/565 (0%)	1/283 (0.35%)
Pancreatic neoplasm [A] †	0/565 (0%)	1/283 (0.35%)
Renal cancer [A] †	1/565 (0.18%)	0/283 (0%)
Renal cancer metastatic [A] †	1/565 (0.18%)	0/283 (0%)
Small cell lung cancer metastatic [A] †	1/565 (0.18%)	0/283 (0%)
Small cell lung cancer stage unspecified [A] †	2/565 (0.35%)	0/283 (0%)

	Degarelix 240 mg/480 mg	Goserelin Acetate
	Affected/At Risk (%)	Affected/At Risk (%)
Squamous cell carcinoma of skin [A] †	1/565 (0.18%)	0/283 (0%)
Thyroid cancer [A] †	1/565 (0.18%)	0/283 (0%)
Tumour local invasion [A] †	1/565 (0.18%)	0/283 (0%)
Nervous system disorders		
Carotid artery stenosis [A] †	1/565 (0.18%)	0/283 (0%)
Cerebrovascular accident [A] †	1/565 (0.18%)	0/283 (0%)
Encephalopathy [A] †	0/565 (0%)	1/283 (0.35%)
Haemorrhagic stroke [A] †	0/565 (0%)	1/283 (0.35%)
Ischaemic stroke [A] †	3/565 (0.53%)	1/283 (0.35%)
Parkinson's disease [A] †	1/565 (0.18%)	0/283 (0%)
Presyncope [A] †	0/565 (0%)	1/283 (0.35%)
Syncope [A] †	3/565 (0.53%)	0/283 (0%)
Transient ischaemic attack [A] †	1/565 (0.18%)	0/283 (0%)
Psychiatric disorders		
Delirium [A] †	0/565 (0%)	1/283 (0.35%)
Renal and urinary disorders		
Acute prerenal failure [A] †	1/565 (0.18%)	0/283 (0%)
Calculus bladder [A] †	1/565 (0.18%)	1/283 (0.35%)
Haematuria [A] †	1/565 (0.18%)	1/283 (0.35%)
Renal failure [A] †	1/565 (0.18%)	0/283 (0%)
Renal failure acute [A] †	1/565 (0.18%)	1/283 (0.35%)
Renal failure chronic [A] †	0/565 (0%)	1/283 (0.35%)

	Degarelix 240 mg/480 mg	Goserelin Acetate
	Affected/At Risk (%)	Affected/At Risk (%)
Urinary retention [A] †	2/565 (0.35%)	1/283 (0.35%)
Urinary tract obstruction [A] †	1/565 (0.18%)	0/283 (0%)
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease [A] †	2/565 (0.35%)	2/283 (0.71%)
Haemoptysis [A] †	1/565 (0.18%)	1/283 (0.35%)
Lung disorder [A] †	1/565 (0.18%)	0/283 (0%)
Pleural effusion [A] †	1/565 (0.18%)	0/283 (0%)
Pleurisy [A] †	1/565 (0.18%)	0/283 (0%)
Pulmonary embolism [A] †	4/565 (0.71%)	3/283 (1.06%)
Respiratory failure [A] †	0/565 (0%)	1/283 (0.35%)
Vascular disorders		
Deep vein thrombosis [A] †	1/565 (0.18%)	0/283 (0%)
Hypertension [A] †	1/565 (0.18%)	0/283 (0%)
Peripheral embolism [A] †	1/565 (0.18%)	1/283 (0.35%)
Peripheral ischaemia [A] †	1/565 (0.18%)	0/283 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 13.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Degarelix 240 mg/480 mg	Goserelin Acetate
	Affected/At Risk (%)	Affected/At Risk (%)
Total	430/565 (76.11%)	197/283 (69.61%)
General disorders		
Fatigue [A] †	27/565 (4.78%)	15/283 (5.3%)

	Degarelix 240 mg/480 mg	Goserelin Acetate
	Affected/At Risk (%)	Affected/At Risk (%)
Injection site erythema [A] †	123/565 (21.77%)	0/283 (0%)
Injection site nodule [A] †	52/565 (9.2%)	0/283 (0%)
Injection site pain [A] †	174/565 (30.8%)	4/283 (1.41%)
Injection site swelling [A] †	36/565 (6.37%)	0/283 (0%)
Oedema peripheral [A] †	13/565 (2.3%)	16/283 (5.65%)
Pyrexia [A] †	31/565 (5.49%)	8/283 (2.83%)
Infections and infestations		
Urinary tract infection [A] †	26/565 (4.6%)	18/283 (6.36%)
Investigations		
Weight increased [A] †	27/565 (4.78%)	24/283 (8.48%)
Musculoskeletal and connective tissue disorders		
Back pain [A] †	23/565 (4.07%)	23/283 (8.13%)
Vascular disorders		
Hot flush [A] †	161/565 (28.5%)	76/283 (26.86%)
Hypertension [A] †	23/565 (4.07%)	20/283 (7.07%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 13.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:
Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The only disclosure restriction on the PI is that the sponsor can review the draft manuscript prior to publication and can request delay of publication where any contents are deemed patentable by the sponsor or confidential to the sponsor. Comments will be given within four weeks from receipt of the draft manuscript. Additional time may be required to allow Ferring to seek patent protection of the invention.

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